

83. (New) An oligonucleotide that hybridizes to a sequence recited in SEQ ID NO:474 under moderately stringent conditions.

84. (New) A diagnostic kit comprising at least one oligonucleotide according to claim 83.

#### REMARKS

Favorable reconsideration of the subject application is respectfully requested in view of the following remarks. Applicants acknowledge that claims 1-3, 13-16, 21-38, 40-43, and 48-76 were withdrawn by the Examiner for being drawn to non-elected inventions. Claims 4, 5, 7-12, 17-20, 39, 44-47, and 77-79 have been cancelled and new claims 80-84 have been added for purposes of clarity and to place this application in better condition for allowance. Claim 6 has been amended to remove reference to non-elected sequences. It is urged that support for all the above new claims may be found throughout the specification as originally filed and that none of the new claims constitutes new matter. Specifically, support for percent identity and contiguous nucleotides can be found, for example, on page 32, line 1 - line 20. Support for moderately stringent hybridization conditions can be found, for example, on page 33, line 3 - line 11. Support for control elements can be found, for example, on page 41, first paragraph. It should also be noted that the above amendments are made without prejudice to prosecution of any or all subject matter modified and/or removed by this amendment in a related divisional, continuation and/or continuation-in-part application.

#### ***Priority***

The Examiner has pointed out that the reference to priority is incorrect. This inadvertent typographical error has been corrected in the above amendment to the specification.

*Rejections under 35 U.S.C. § 112, first paragraph (written description)*

Claims 4, 5, 7-12, 17-20, 39, 44-47, and 77-79 are rejected as allegedly containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The Examiner alleges that the Applicants are not entitled to variant language because the disclosure fails to describe the common attributes or characteristics that identify the members of the claimed genus of polynucleotides.

Applicants respectfully traverse this rejection and submit that the U.S.P.T.O. has indicated that possession of an invention is more readily established, and correspondingly greater claim breadth is permissible, where an applicant discloses functional and/or descriptive information concerning the specie(s) in an application, e.g., a distinguishing identifying characteristic common among the members of a claimed genus (see *Guidelines for Examination of Patent Applications Under the 35 U.S.C. § 112, para. 1, "Written Description" Requirement* - Federal Register: January 5, 2001 (Volume 66, No. 4, pgs. 1099-1111)). For example, at the bottom of pg. 1105, the *Guidelines* state that, "(a)n adequate written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention." The claims as amended recite an isolated polynucleotide comprising a sequence selected from the group consisting of (a) complements of the sequence provided in SEQ ID NO:474; (b) sequences consisting of at least 20 contiguous nucleotides of a sequence provided in SEQ ID NO:474; (c) sequences that hybridize to a sequence provided in SEQ ID NO:474, under moderately stringent conditions; (d) sequences having at least 75% identity to a sequence of SEQ ID NO:474; (e) sequences having at least 90% identity to a sequence of SEQ ID NO:474; and degenerate variants of a sequence provided in SEQ ID NO:474; **wherein said polynucleotide is over-expressed in breast tissue as compared to normal tissue** (emphasis added). Applicants submit that the skilled artisan would readily understand, in light of the applicant's disclosure, the single identifying characteristic common to the claimed polynucleotides, *i.e.*, over-

expression in breast tissue as compared to normal tissue. Thus, it is urged that the pending claims fully satisfy the written description requirement of 35 U.S.C. § 112, first paragraph, and that the rejection of the claims may be properly withdrawn.

***Rejections under 35 U.S.C. § 112, first paragraph (enablement)***

Claims 65-70 are rejected as allegedly containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains to make and/or use the claimed polynucleotide sequences. The Examiner alleges that the claims are not enabled because the use of "pharmaceutical" and "vaccine" language implies *in vivo* use and the specification allegedly lacks sufficient guidance in regard to these issues.

Applicants respectfully traverse this rejection and submit that the instant specification is fully enabling. The specification offers ample guidance on making and using pharmaceutical and vaccine compositions, for example, on page 100, line 3 – page 107, line 9. For purposes of clarity, the newly added claims do not refer to pharmaceutical compositions or vaccines. These terms have been replaced with the generic term "composition". Applicants note that the above amendments are made without prejudice and without acquiescing to the Examiner's rejections. Applicants reserve the right to pursue any or all subject matter modified and/or removed by this amendment in a related divisional, continuation and/or continuation-in-part application. Applicants submit that the specification, as filed, and the amended claims satisfy the enablement requirement of 35 U.S.C. § 112, first paragraph and respectfully urge that the rejection may be properly withdrawn.

***Rejections under 35 U.S.C. § 112, second paragraph (indefiniteness)***

Claims 44-47 were rejected under 35 U.S.C. § 112, second paragraph as being indefinite. The examiner points out that the claims lack antecedent basis. Applicants submit that this was due to a typographical error in the dependency. Claims

44-47 should depend from claim 39. Applicants further submit that the present amendment obviates this ground for rejection and respectfully request its withdrawal.

***Claim Objections***

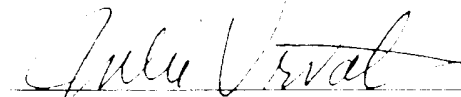
Claim 9 is objected to for the recitation of the phrase "claims claim", an obvious typographical error. Applicants have corrected this error in the newly rewritten claim 81.

Claim 6 is objected to for the recitation of non-elected sequences. Applicants note that the Examiner has found that claim 6 is free of the prior art searched. Applicants further submit that claim 6 has been amended to remove all reference to non-elected sequences and to clarify that the Applicants' invention is directed to an isolated polynucleotide comprising at least the coding region of SEQ ID NO:474. Therefore, Applicants respectfully request favorable reconsideration of the objection.

Favorable reconsideration and allowance of the pending claims are respectfully requested. The Examiner is invited to contact the undersigned with any questions, concerns or suggestions pertaining to this communication.

Respectfully submitted,

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## VERSION WITH MARKINGS TO SHOW CHANGES

In the specification:

The first paragraph on page 1 has been deleted and replaced with a corrected paragraph as follows:

~~This application is a continuation-in-part of U.S. Patent Application No. 09/433,836, filed on November 3, 1999, which is a continuation-in-part of U.S. Application No. 09/389,681, filed on September 2, 1999, which is a continuation-in-part of U.S. Application No. 09/389,338, filed on June 23, 1999, which is a continuation-in-part of U.S. Application No. 09/285,480, filed on April 2, 1999, which is a continuation-in-part of U.S. Application No. 09/222,575, filed December 28, 1998.~~

This application is a continuation-in-part of U.S. Patent Application No. 09/433,826, filed on November 3, 1999, which is a continuation-in-part of U.S. Application No. 09/389,681, filed on September 2, 1999, which is a continuation-in-part of U.S. Application No. 09/339,338, filed on June 23, 1999, which is a continuation-in-part of U.S. Application No. 09/285,480, filed on April 2, 1999, which is a continuation-in-part of U.S. Application No. 09/222,575, filed December 28, 1998.

In the claims:

Claims 4, 5, 7-12, 17-20, 39, 44-47, and 77-79 have been cancelled.

Claim 6 has been amended as follows:

6. An isolated polynucleotide comprising at least the coding region of a sequence recited in any one of SEQ ID NOS: 2, 4-15, 18-33, 35-47, 49-56, 58, 59, 63-73, 88-116, 141-159, 175, 178, 180, 185, 186, 194, 199, 205, 208, 211, 214-216, 219, 222, 226, 232, 236, 240, 241, 245, 246, 252-268, 320-324, 342, 353, 366-368, 377, 382,

~~385, 389, 395, 397, 400, 408, 411, 413, 414, 416, 417, 419-423, 426, 427, 429, 431, 435-438, 441, 443-446, 450, 453, 454, 463-468 and 474.~~

New claims 80-84 have been added.

80. (New) An isolated polynucleotide comprising a sequence selected from the group consisting of:

- (a) complements of the sequence provided in SEQ ID NO:474;
  - (b) sequences consisting of at least 20 contiguous nucleotides of a sequence provided in SEQ ID NO:474;
  - (c) sequences that hybridize to a sequence provided in SEQ ID NO:474, under moderately stringent conditions;
  - (d) sequences having at least 75% identity to a sequence of SEQ ID NO:474;
  - (e) sequences having at least 90% identity to a sequence of SEQ ID NO:474; and
  - (f) degenerate variants of a sequence provided in SEQ ID NO:474;
- wherein said polynucleotide is over-expressed in breast tissue as compared to normal tissue.

81. (New) An expression vector comprising a polynucleotide of claim 6 or claim 80 operably linked to an expression control element.

82. (New) A composition comprising a first component selected from the group consisting of physiologically acceptable carriers and immunostimulants, and a second component comprising a polynucleotide according to claim 6 or claim 80.

83. (New) An oligonucleotide that hybridizes to a sequence recited in SEQ ID NO:474 under moderately stringent conditions.

84. (New) A diagnostic kit comprising at least one oligonucleotide

according to claim 83.